N0N-TECHNICAL ABSTRACT

NIH OBA Protocol Application

Protocol #	NYU 07-790 (LUD2007-005)
Principal Investigator:	Nina Bhardwaj, MD, PhD
Title:	Phase 1 study of ALVAC(2)-NY-ESO-1(M)/TRICOM (vCP2292) in patients with epithelial ovarian, fallopian tube or primary peritoneal carcinoma whose tumors express NY-ESO-1 or LAGE-1 antigen. Version 002 Amendment 2 16-MAY-2008 (Issue Date)

The purpose of this study is to test the safety of a vaccine in patients with ovarian cancer or similar tumors such as cancer of the fallopian tube or cancer of the peritoneum, also known as primary peritoneal cancer. Patients are being asked to participate in this study because they have ovarian cancer or similar tumors such as cancer of the fallopian tube or cancer of the peritoneum.

The usual treatment for ovarian, fallopian tube or primary peritoneal cancer using chemical compounds (chemotherapy) or radiation (radiotherapy) is not always successful and the cancer often recurs after a period of time. The standard approach for the treatment of these types of cancer is surgery and chemotherapy. At the present time, there is no proven additional treatment given after surgery and chemotherapy that will effectively delay the return of cancer. However, a new type of cancer treatment called gene therapy is available to provide genes that correct or replace the disease-controlling functions of cells that are not doing their job. Genes are the basic physical and functional units of heredity; also referred to as DNA sequences [chains] that are copied to produce a functional product. Classic gene therapy involves inserting a functional gene or DNA fragment into key cells to *potentially* mitigate or cure a disease. In addition, immunotherapy is being tested to activate the body's immune system to react against cancer cells. The vaccine in this study is called recombinant canarypox-NY-ESO-1/TRICOM [or ALVAC(2)-NY-ESO-1(M)/TRICOM].

Patients may qualify for this study if they have received initial treatment for their cancer that included both surgery and chemotherapy and are now in "clinical remission", meaning they have no evidence of cancer evidenced by physical examination, CA125 (a blood test and marker for ovarian cancer) and CT scan; or, their cancer might have returned, and they have now completed additional chemotherapy, and currently are in "clinical remission" or have still some cancer remaining (by physical examination, blood test or CT scan).

To qualify for this study, the patient's tumor MUST express a certain antigen called NY-ESO-1 or LAGE-1. This is important as the vaccine is designed to stimulate the immune system against this antigen. To test if the patient's tumor expresses this antigen, left-over tumor tissue from the patient's past surgery will be obtained from the NYU pathology department, and stained. Approximately, 40% of ovarian tumors express the antigen and only patients with tumors expressing this antigen can enter this study.

The vaccine in this study **(ALVAC(2)-NY-ESO-1(M)/TRICOM)** contains the protein (antigen, NY-ESO-1) in a recombinant canary pox virus. The canary pox virus is a virus that can reproduce in birds but not in humans. It has been used safely in many vaccine studies before and does not cause any known disease in humans. It can stimulate the immune system and can carry antigens and additional immune boosters (such as TRICOM). Antigens (such as NY-ESO-1) are found on many cancer cells. An additional immune booster **(GM-CSF)** is given to the patient after vaccination to increase the strength of the vaccine. The hope is that the vaccine will cause the patient's immune system to produce immune cells and antibodies (proteins) that will help locate NY-ESO-1 on cancer cells. The immune system could then work to control or maybe eliminate the remaining cancer cells. Other similar vaccines have been tested in various tumors. While some patients make immune cells and antibodies to the vaccines, it is too early to know if the vaccines are helpful in preventing cancer from returning.

The main purpose of this research is to study the safety of this vaccine approach. However, the researchers will also look whether this vaccine can make the body form an immune response and whether it helps to fight the cancer.